

Notice to Readers: Inadvertent Intradermal Administration of Tetanus Toxoid--Containing Vaccines Instead of Tuberculosis Skin Tests

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Notice to Readers: Inadvertent Intradermal Administration of Tetanus Toxoid--Containing Vaccines Instead of Tuberculosis Skin Tests CDC and the Food and Drug Administration (FDA) have been notified about the potential for inadvertent administration of tetanus toxoid--containing vaccines (TTCVs) instead of tuberculin purified protein derivative (PPD) (Tubersol®, Aventis-Pasteur, Swiftwater, Pennsylvania; Aplisol®, Parkedale Pharmaceuticals, Rochester, Michigan) used for tuberculosis skin tests (TSTs). The Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system jointly operated by CDC and FDA (1), detected clusters of medication errors in at least two states. These findings, along with another previously reported investigation involving the same error (2), suggest the need for health-care providers to take additional steps to minimize the risk for inadvertent intradermal injections of TTCVs.

In April 2004, five reports of medication error involving tetanus toxoid (TT) from a health-care provider were identified. Patients were vaccinated on three different dates; all experienced local reactions without complications. Another cluster reported to VAERS in June 2003 involved an undisclosed number of patients; a health-care provider confused tetanus and diphtheria toxoids (Td) vaccine for adult use (adsorbed) with PPD and administered Td intradermally. Patients with adverse reactions to these administrations had skin reactions interpreted as positive TSTs, which resulted in treatment with isoniazid (INH). Review of the lot numbers on products thought to be PPD revealed they were Td. Affected patients were identified and retested with PPD; all TSTs were negative. INH was discontinued, and no adverse reactions were observed.

As of March 2004, approximately 100 patients had been identified in reports of TTCV administration instead of PPD. A total of 21 states have reported both clusters and single cases. Vaccines substituted mistakenly for PPD include Td (n = 13 reports), TT (n = 12), and diphtheria and tetanus toxoids, (DT) adsorbed (n = five). For reports of Td, TT, and DT, products involved included those manufactured by Aventis-Pasteur and Wyeth (Collegeville, Pennsylvania) and vaccines from other unspecified manufacturers. CDC and FDA have initiated a full review of adverse events caused by inadvertent administration of vaccines and PPD products reported to VAERS and the FDA MedWatch Program. A preliminary review indicates that multiple vaccines other than TTCVs have been involved.

Similarities in packaging of PPD and TTCVs might have contributed to the medication errors (3,4). Both products require refrigeration and often are stored side by side. Lack of availability of Td in single-dose syringes, resulting in provider purchase of multiple-dose vials, was cited as a contributing factor to medication error in one cluster. Conversely, at least eight reports have been

documented of inadvertent substitution for vaccine products, resulting in intramuscular administration of PPD (FDA, unpublished data, 2004).

Health-care providers should consider ways to prevent vaccine misadministration. As more vaccines and combination products become available, the potential for medication errors might increase. Possible measures to prevent misadministration should include pharmacy dispensing of vaccines when feasible, physical separation of products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of vaccines and other injectable products. Prevention of such errors through barcode scanning technology is the goal of a recent FDA rule requiring individual drug packages to have identifying barcodes (5). For health-care facilities that possess such technology, package scanning could help prevent errors made during pharmacy dispensing of products or during vaccine or PPD administration. In addition, the Product Identification Guide for Routine Vaccines is a helpful resource for distinguishing commonly used vaccine products; the guide can be ordered from the California Department of Health Services, telephone 619-594-5933. Adverse events associated with inadvertent vaccine administration can be reported to VAERS at <http://www.vaers.org> or by telephone, 800-822-7967. Adverse events after PPD administration can be reported to the FDA MedWatch program at <http://www.fda.gov/medwatch> or by telephone, 800-332-1088.

References

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